APPENDIX

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently amended): An immunogenically active component useful for preventing or ameliorating equine protozoal myoencephalitis infection or disease which comprises ~~a member selected from the group consisting of~~ merozoite antibody-inducing[[,]] inactivated *Sarcocystis neurona* cells[[;]], tachyzoite antibody-inducing[[,]] inactivated *Neospora hughesi* cells[[;]], a merozoite ~~or tachyzoite~~ antibody-inducing antigen derived from said *Sarcocystis neurona* cells[[;]], a tachyzoite antibody-inducing antigen derived from said *Neospora hughesi* cells, plasmid DNA obtained from a horse diagnosed to have equine protozoal myoencephalitis that is derived from *Sarcocystis neurona* ~~said cells capable of inducing a merozoite or tachyzoite antibody immune response~~[[;]] or *Neospora hughesi*, or ~~and~~ a mixture thereof.

Claim 2 (Currently amended): The component according to claim 1 which comprises merozoite antibody-inducing inactivated *Sarcocystis neurona* cells[[;]], ~~an~~ the antigen derived from said cells[[;]], plasmid DNA obtained from the horse diagnosed to have equine protozoal myoencephalitis derived from said cells[[;]] or a mixture thereof.

Claim 3 (Withdrawn - currently amended): The component according to claim 1 which comprises tachyzoite antibody-inducing inactivated *Neospora hughesi* cells[[;]], ~~an~~ the antigen derived from said cells[[;]], plasmid DNA obtained from the horse diagnosed to have equine protozoal myoencephalitis derived from said cells[[;]] or a mixture thereof.

Claim 4 (Currently amended): The component according to claim 1 wherein said active component comprising merozoite antibody-inducing, inactivated *Sarcocystis neurona* cells, tachyzoite antibody-inducing inactivated *Neospora hughesi* cells or the mixture of the inactivated *Sarcocystis neurona* cells and the inactivated *Neospora hughesi* cells is present in sufficient quantity to provide at least $1x10^4$ inactivated cells per dosage unit ~~dose~~ form.

Claim 5 (Currently amended): A vaccine composition for the prevention or amelioration of equine protozoal myoencephalitis infection or disease in equines which comprises a therapeutically ~~an~~ effective ~~immunizing~~ amount of the immunogenically active component of claim 1, a pharmacologically acceptable carrier[[;]] and optionally an immunogenically stimulating adjuvant.

Claim 6 (Currently amended): The vaccine composition according to claim 5 wherein said active component comprising merozoite antibody-inducing, inactivated *Sarcocystis neurona* cells, tachyzoite antibody-inducing inactivated *Neospora hughesi* cells or the mixture of the inactivated *Sarcocystis neurona* cells and the inactivated *Neospora hughesi* cells is present in sufficient quantity to provide at least $1x10^4$ inactivated cells per dosage unit ~~dose~~ form.

Claim 7 (Currently amended): The vaccine composition according to claim 5 wherein said active component comprising merozoite antibody-inducing, inactivated *Sarcocystis neurona* cells, tachyzoite antibody-inducing inactivated *Neospora hughesi* cells or the mixture of the inactivated *Sarcocystis neurona* cells and the inactivated *Neospora hughesi* cells is present in sufficient quantity to provide at least $1x10^6$ inactivated cells per dosage unit ~~dose~~ form.

Claim 8 (Currently amended): The vaccine composition of claim [[2]] 5 wherein said active component comprising merozoite antibody-inducing inactivated *Sarcocystis neurona* cells, the antigen derived from said cells, the plasmid DNA obtained from the horse diagnosed to have equine protozoal myoencephalitis derived from said cells or the mixture thereof is present in an amount sufficient to produce a merozoite inducing serum neutralizing antibody response which ~~is protozocidal~~ has a neutralizing effect on *Sarcocystis neurona* merozoites.

Claim 9 (Withdrawn - currently amended): The vaccine composition of claim [[3]] 5 wherein said active component comprising tachyzoite antibody-inducing inactivated *Neospora hughesi* cells, the antigen derived from said cells, the plasmid DNA obtained from the horse diagnosed to have equine protozoal myoencephalitis derived from said cells or the mixture thereof is present in an amount sufficient to produce a tachyzoite inducing serum neutralizing antibody

response which ~~is protozocidal~~ has a neutralizing effect on *Neospora hughesi* tachyzoites.

Claim 10 (Currently amended): The vaccine composition according to claim 5 wherein the immunogenically stimulating adjuvant is present at about 1% to 50% by weight ~~wt/wt~~.

Claim 11 (Currently amended): The vaccine composition according to claim 10 wherein said adjuvant is present at about 5% to 20% by weight ~~wt/wt~~.

Claim 12 (Currently amended): The vaccine composition according to claim 10 wherein said active component comprises merozoite antibody-inducing inactivated *Sarcocystis neurona* cells.

Claim 13 (Original): The vaccine composition according to claim 12 wherein said adjuvant is a metabolizable oil.

Claim 14 (Original): The vaccine composition according to claim 13 wherein the pharmacologically acceptable carrier is a balanced salt solution.

Claim 15 (Withdrawn - currently amended): A vaccine composition for the prevention or amelioration of ~~EPM~~ equine protozoal myoencephalitis disease in equines comprising[[,]]:
- a first immunogenically active component ~~selected from the group consisting of~~ comprising merozoite antibody-inducing[[,]] inactivated *Sarcocystis neurona* cells[[;]], a merozoite antibody-inducing antigen derived from said cells[[;]],plasmid DNA obtained from a horse diagnosed to have equine protozoal myoencephalitis that is derived from said cells capable of inducing a merozoite antibody immune response[[;]] or a mixture thereof[[;]],
- a second immunogenically active component ~~selected from the group consisting of~~ comprising tachyzoite antibody-inducing[[,]] inactivated *Neospora hughesi* cells[[;]], a tachyzoite antibody-inducing antigen derived from said cells[[;]], plasmid DNA obtained from a horse diagnosed to have equine protozoal myoencephalitis that is derived from said cells capable of inducing a tachyzoite antibody immune response[[;]] or a mixture thereof[[;]],

- a pharmacologically acceptable carrier[[;]] and optionally an immunogenically stimulating adjuvant.

Claim 16 (Withdrawn - currently amended): The vaccine composition according to claim 15 wherein said first immunologically active component comprises the inactivated *Sarcocystis neurona* cells and said second immunologically effective component comprises the inactivated *Neospora hughesi* cells.

Claim 17 (Withdrawn - currently amended): The vaccine composition according to claim 15 wherein said first immunologically active component is present in an amount sufficient to produce a ~~merezoite~~ merozoite inducing serum neutralizing antibody response which ~~is protozocidal~~ has a neutralizing effect on *Sarcocystis neurona* merozoites, and wherein said second immunologically active component is present in an amount sufficient to produce a tachyzoite inducing serum neutralizing antibody response which ~~is protozocidal~~ has a neutralizing effect on *Neospora hughesi* tachyzoites.

Claim 18 (Withdrawn - currently amended): A method for the prevention or amelioration of ~~EPM~~ equine protozoal myoencephalitis disease in equines which comprises administering to said equine ~~an~~the immunogenically active component of claim 1 ~~which comprises a member selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a merozoite or tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merezoite or tachyzoite antibody immune response; or a mixture thereof~~.

Claim 19 (Withdrawn - currently amended): A method for the prevention or amelioration of ~~EPM~~ equine protozoal myoencephalitis disease in equines which comprises administering to said equine a therapeutically effective amount of ~~a~~ the vaccine composition of claim 5 ~~which comprises, an effective immunizing amount of an immunogenically active component which comprises a member selected from the group consisting of merezoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora*~~

~~*hughesi* cells; a merezoite or tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merezoite or tachyzoite antibody immune response; or a mixture thereof; and a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.~~

Claim 20 (Withdrawn - currently amended): A method for the prevention or amelioration of ~~EPM~~ equine protozoal myoencephalitis disease in equines which comprises administering to said equine ~~a~~ the vaccine composition of claim 15 ~~which comprises;~~

~~- a first immunogenically active component selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; a merozoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merozoite antibody immune response; or a mixture thereof;~~

~~- a second immunogenically active component selected from the group consisting of tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a tachyzoite antibody immune response; or a mixture thereof;~~

~~a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.~~

Claim 21 (Withdrawn - currently amended): The method according to claim [[18]] 19 wherein said vaccine is administered parenterally.

Claim 22 (Withdrawn - currently amended): The method according to claim [[18]] 19 wherein said vaccine is administered intramuscularly.

Claims 23-25 (Canceled).

ATCC

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Fort Dodge Animal Health
Attn; Joseph W. Whalen Jr.
800 5th Street N.W.
Fort Dodge, IA 50501

Deposited on Behalf of: Fort Dodge Animal Health, A Division of American Home Products

Identification Reference by Depositor: **Patent Deposit Designation**
Sarcocystis neurona propagated in E. Dermal cells: Sarcocystis neurona PTA-2972

The deposit was accompanied by: __ a scientific description __ a proposed taxonomic description indicated above.

The deposit was received January 25, 2001 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

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